510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device

Food and Drug Administration

Center for Devices and Radiological Health

Meeting Purpose

- FDA will submit report on 510(k) Modifications policy to Congress by January, 2014
- Report must explain how to determine when a 510(k) is required for a device change
- Report will explain how FDA plans to maintain effective oversight of modified devices, while allowing industry freedom to innovate efficiently

Meeting Agenda

- FDA Background Presentation
- Foreign Modifications Policies – Canada and EU
- External Stakeholder Presentations from industry and consumer representatives
- Panel Discussion:
  - FDA
  - Industry Representatives
  - Consumer Representatives
  - Patient Representatives
  - CMS

Meeting Participants

- Foreign Regulatory Bodies
  - Health Canada: Ian Aldous, PhD
  - BSI: Paul Brooks
- Consumer Representation
  - Monica Harmon, MSN, MPH, RN
  - Lisa Swirsky, JD
  - Diana Zuckerman, PhD
- Industry Representation
  - Elisabeth George
  - Ralph Hall, JD
  - Tamima Itani, PhD
  - April Veoukas, JD
  - Diane Wurzburger
- Regulatory Consultant Representation
  - Craig Coombs
- Patient Representation
  - Philip Posner, PhD
- Other Government Agency Representation
  - CMS: Louis Jacques, MD
- FDA
  - Tony Chan, DRSc, MBA, MSQA
  - Geeta Pamidimukkula, MS
  - Michael Ryan
  - Nancy Stade, JD
  - Keisha Thomas

When a 510(k) is Required for a Change

- 21 CFR 807.81(a)(3): The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:
  - (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
  - (ii) A major change or modification in the intended use of the device.

Key Concepts

- Significant changes are those that *could* significantly affect safety or effectiveness
- Significant changes can be positive or negative
- While there are certain types of changes that will almost always need a 510(k), most changes are dependent on circumstances
- FDA usually only sees changes that do result in 510(k)s – need more info from industry

Is a Policy Change Necessary?

- Current guidance is from 1997 – 16 years ago

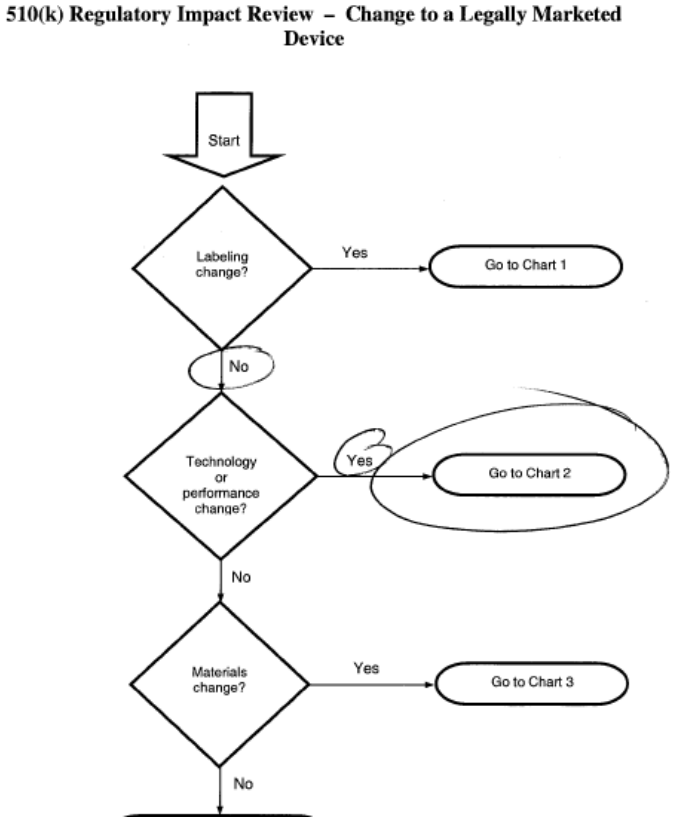
- Modifications – even simple ones – can lead to public health issues

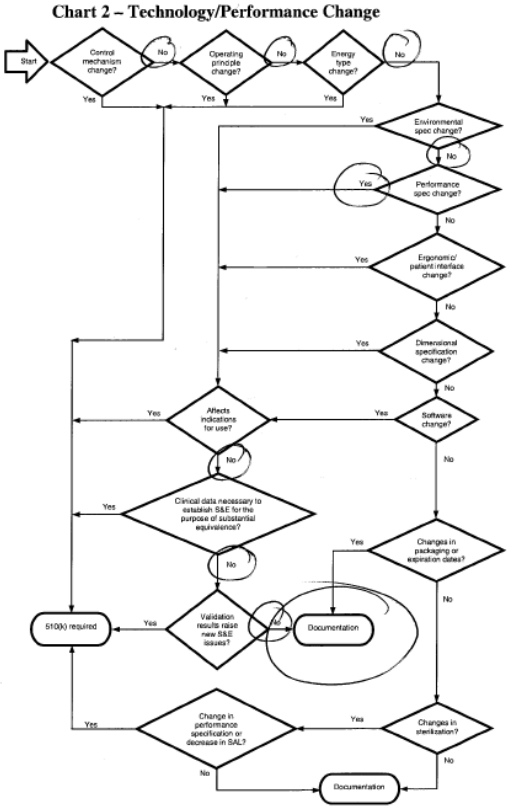
1997 Then and Now

Problematic Changes

- Recall of Waste Management System
  - Two reports of serious injury as a result of tissue damage associated with the use of waste management devices, including a fatality
  - Following an inspection, FDA advised the company that recalled devices require, but do not currently have, 510(k) clearance
  - Inspection also found inadequate design change records as required by 820.30(i)

Documentation Issues





Documentation Issues

6. FDA 510 (K) Pre-Market Notification In the review of the changes incorporated in this design document, we have asked and answered the following questions:

Do the changes incorporated in this design affect indications for use? NO (yes or no)

Are clinical data necessary to evaluate safety and effectiveness for purposes of determining substantial equivalence? NO (yes or no)

Do results of design validation raise new issues of safety and effectiveness? NO (yes or no)

- Manufacturers aren't always following the current guidance document
- Manufacturers aren't always documenting appropriately, which makes effective regulatory oversight more difficult

Is a Policy Change Necessary?

- Technology is more complex now, and regulatory guidance needs to keep up
  - Need to account for new and evolved technologies, such as WiFi and batteries
  - Need to update policy on evolved technologies, such as batteries
- Consistency across industry is an issue
  - Different business units of same company sometimes come to different decisions
  - While many companies get these decisions right, many do not

The Ultimate Goal

- Industry needs to be able to update their devices without having to submit for every single change
- Patients and consumers need assurance that modified devices are as S&E as predicate devices
- All stakeholders need a decision-making process they can rely on for accuracy and consistency

Today's Topics of Discussion

- Potential use of risk management
- Potential reliance on design control activities
- Potential use of critical specifications
- Potential risk-based stratification of medical devices
- Potential periodic reporting

Potential Use of Risk Management

- Can FDA and industry incorporate risk management into the decision to submit?
  - Risk threshold?
  - Use of risk to help define “could significantly affect” and “major change or modification?”

Risk Management Concerns

- Risk management is a process, not a "when to submit" calculator
- There are many different ways to do risk management
- Risk management analyses inherently involve subjectivity
- Risk management processes must be comprehensive and appropriately implemented

Potential Reliance on Design Control Activities

- Can FDA and industry rely more on design control activities to reduce the need to submit 510(k)s?

Reliance on Design Controls Concerns

- FDA generally only reviews design control info during directed inspections, which are limited due to resources. How can FDA ensure that design control activities will limit the potential for marketing of device modifications that may be unsafe or ineffective?
- Although 21 CFR 820.30 imposes the same design control requirements on all medical device manufacturers, the ways in which manufacturers comply with these requirements vary. How can FDA ensure consistency in use of design controls to ensure that only safe and effective modified devices are marketed?

Potential Use of Critical Specifications

- Possible link between Quality Systems and 510(k) modification decisions
- Manufacturers would proactively identify:
  - Types of changes they might make
  - Which specifications are critical for those types of changes
  - Specification bounds
  - Verification & validation test protocols to examine the identified critical specifications

Critical Specifications Example

- Change of an implant material
  - Critical specifications might include tensile strength, 950 MPa ± 15 MPa, tested with a certain protocol
  - Any new material used in that implant would have to demonstrate a tensile strength of 935-965 MPa
  - Within that range, no 510(k) would be required; outside of that range, a 510(k) would be required

Critical Specifications Concerns

- Review of critical specs would require review time and resources and would affect the review process in many different ways
- Where and when should critical specifications be used?
  - Limit to certain types of changes?
  - Limit to certain types of devices?
  - Should this be an optional paradigm?

Potential Risk-Based Stratification

- Is it practical to stratify higher and lower risk 510(k) devices in a way that modifications to lower risk devices would not typically require a 510(k)?
  - FDA would still expect 510(k)s for certain higher risk changes to lower risk devices
  - Some other measure, such as periodic reporting, may be required for lower risk devices to maintain effective regulatory oversight

Risk-Based Stratification Concerns

- How should FDA delineate higher versus lower risk devices?
- Should FDA require some other measure, such as periodic reports, for modified lower risk devices in lieu of 510(k) submissions?
- Because modifications to lower risk devices could still result in harm or injury, FDA believes that some modifications to lower risk devices should still be reviewed in 510(k) submissions prior to marketing

Potential Periodic Reporting

- Is it practical to require periodic reports for modifications to 510(k)-cleared devices?
  - Would allow FDA to ensure that modifications are being appropriately submitted and reviewed
  - Over time, periodic reporting would give FDA a more complete picture of the changes industry is making to 510(k)-cleared devices, and may allow FDA to tailor 510(k) modifications requirements to ensure that the Agency is reviewing only the changes it needs to in new 510(k) submissions

Periodic Reporting Concerns

- Periodic reporting would require additional FDA and industry resources, unless combined with fewer 510(k) modification submissions
- It's unclear how often reports should be made, what info they should contain, and how they should be reviewed

Other Policy Proposals

- Any one of the above options may be insufficient on its own; best solution may be a combination of options
- Other options may exist that have not been identified above

Other Policy Proposals

- Any policy must ensure:
  - Consistent decision-making by both industry and FDA
  - Effective oversight of modified devices, especially those that could significantly affect safety or effectiveness

Conclusion

- FDA is looking to improve 510(k) modifications policy
- The Agency only sees part of the story – we need external stakeholders to help fill in the blanks
- FDA seeks detailed, practical proposals, both throughout the day, and in writing at www.regulations.gov by July 13
  - Search for “FDA-2013-N-0430” and select “Comment Now!”